964 F. Supp. 413, \*; 1997 U.S. Dist. LEXIS 8294, \*\*

PUBLIC CITIZEN HEALTH RESEARCH GROUP, Plaintiff, v. FOOD AND DRUG ADMINISTRATION, Defendant.

Civil Action No. 96-1650 (JR)

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

964 F. Supp. 413; 1997 U.S. Dist. LEXIS 8294

February 24, 1997, Decided February 25, 1997, FILED

#### **CASE SUMMARY**

**PROCEDURAL POSTURE:** Plaintiff public interest group filed an action against defendant Food and Drug Administration (FDA) under the Freedom of Information Act, 5 U.S.C.S. § 552. The public interest group sought access to the protocol for a post-marketing study of a drug used to help control diabetes. Defendant manufacturer intervened to help the FDA resist disclosure. All parties filed motions for summary judgment.

OVERVIEW: As a condition of its approval of the drug, the FDA required the manufacturer to conduct a post-marketing study of 10,000 patients. The protocol for the study was approved by the FDA but was not made public. The FDA denied the public interest group's request for the protocol on the ground that the requested documents contained confidential information exempt from disclosure under 5 U.S.C.S. § 552(b) (4). The count noted that commercial information was confidential if disclosure was likely to impair the government's ability to obtain necessary information in the future or cause substantial harm to the competitive position of the person who submitted the information. The court held that the FDA's conclusory assertion of impairment did not sustain its burden of justifying nondisclosure. In order to support withholding under the competitive harm prong, the party opposing disclosure had to show actual competition and likelihood of substantial competitive injury. The court held that the likelihood of substantial competitive injury could not be measured or even plainly identified on the record. Accordingly, the court directed the FDA to submit a copy of the protocol for in camera reviews garde to a first and supplies on the term of the action of the contract of the

**OUTCOME:** The court directed the FDA to submit a copy of the protocol for in camera review. The court ordered that the manufacturer could file an additional memorandum, ex parte and under seal, identifying precisely the portions of the protocol that contained confidential commercial information that was not already public.

**CORE TERMS:** protocol, disclosure, competitive, confidential, memorandum, competitor, regulation, patient, summary judgment, exemption, post-marketing, diabetes, in camera, impairment, manufacturer, non-insulin, withholding, side-effects, releasing, publicly, mellitus, prong, ex parte, pre-approval, marketing, therapy, seal

# LexisNexis(R) Headnotes \* Hide Headnotes

Administrative Law > Governmental Information > Freedom of Information 

Exemption 4 of the Freedom of Information Act, 5 U.S.C.S. § 552, protects (i) commercial or financial information (ii) obtained from a person (iii) that is privileged or confidential. 5 U.S.C.S. § 552(b)(4). Commercial information is confidential if disclosure is likely to (i) impair the government's ability to

confidential if disclosure is likely to (i) impair the government's ability to obtain necessary information in the future; or (ii) cause substantial harm to the competitive position of the person who submitted the information. More Like This Headnote

<u>Like This Headnote</u>

Administrative Law > Governmental Information > Freedom of Information

The Food and Drug Administration's regulations implementing the Freedom of Information Act provide that no data or information contained in a new drug application is available for public disclosure before the agency sends an approval letter to the sponsor. 21 C.F.R. § 314.430(d). Once an approval letter has been sent, certain data and information are immediately available for disclosure unless the applicant shows that exceptional circumstances exist. 21 C.F.R. § 314.430(e). Study protocols are expressly covered by the regulations and are immediately disclosable unless they fall within the exemption established for trade secrets and confidential commercial information. 21 C.F.R. § 314.430(e)(3). More Like This Headnote

Administrative Law > Governmental Information > Freedom of Information Information Information Information > Information Information > Information | Informa

Administrative Law > Governmental Information > Freedom of Information

In order to support a decision to withhold disclosure under the Freedom of Information Act based on the requirement that disclosure would cause substantial harm to the competitive position of the person who submitted the information, the party seeking to avoid disclosure must show (i) actual competition and (ii) likelihood of substantial competitive injury. No showing of competitive harm can be made if the information at issue is publicly available through other sources. An additional factor that may be considered is whether there is a strong public interest in release of the information. More Like This Headnote

**COUNSEL:** [\*\*1] Lucinda A. Sikes, Allison Zieve, Public Citizen Litigation Group, Washington, DC, Counsel for Plaintiff.

Suzanne C. Nyland, Assistant U.S. Attorney Washington, DC, Counsel for Defendant.

Terry S. Coleman, Fox, Bennett & Turner, Washington, DC, Counsel for Intervenor-Defendant Bristol-Myers Squibb Company.

JUDGES: JAMES ROBERTSON, United States District Judge

**OPINIONBY: JAMES ROBERTSON** 

OPINION: [\*414] MEMORANDUM

Plaintiff seeks access under the Freedom of Information Act, <u>5 U.S.C. § 552</u>, to the protocol for a 10,000 patient post-marketing study of the drug Metformin. Bristol-Myers Squibb, the manufacturer of Metformin, has intervened to help the FDA resist disclosure. All parties have moved for summary judgment. Oral argument was presented on January 27, 1997, and the parties were afforded an opportunity to file post-hearing briefs. None of the motions for summary judgment can be granted. The record in its present state of development does not permit findings as to whether the protocol in fact contains confidential commercial information and, if it does, as to whether portions of the protocol may be released without compromising information that is entitled to protection.

#### Background [\*\*2]

Metformin is an oral anti-hyperglycemic drug used to help control non-insulin dependent diabetes mellitus. The Food and Drug Administration approved Metformin on December 29, 1994, pursuant to 21 U.S.C. § 355(a). As a condition of its approval, FDA required BMS to conduct a post-marketing study of 10,000 patients. Little is publicly known of the study except that it focuses on the incidence of lactic acidosis and cardiovascular deaths, as well as unstudied side-effects. The study is in progress, but its duration and status are not known. The BMS protocol for the study -- the outline of clinical objectives, the study design, and the working hypotheses -- was approved by the FDA but has not been made public

Plaintiff made its FOIA request for the protocol on June 5, 1996. FDA denied the request on the ground that the requested documents contained confidential commercial information exempt from disclosure under 5 U.S.C. § 552(b)(4).

#### **Analysis**

HNI\*Exemption 4 protects (i) commercial or financial information (ii) obtained from a person (iii) that is privileged or confidential. 5 U.S.C. § 552(b)(4); National Parks & Conservation Ass'n v. Morton, 162 U.S. App. D.C. 223, 498 [\*\*3] F.2d 765 (D.C. Cir. 1974). n1 The only disputed element is whether the information is "confidential." Commercial information is confidential if disclosure is likely to (i) impair the government's ability to obtain necessary information in the future; or (ii) cause substantial harm to the competitive position of the person who submitted the information. National Parks, 498 F.2d at 770. FDA and BMS argue that both definitions apply and mandate withholding of the protocol.

n1 The National Parks test is applicable because the challenged information was required to be submitted. See <u>Critical Mass Energy Project v. Nuclear Regulatory Commission, 298 U.S. App. D.C. 8, 975 F.2d 871, 878 (D.C. Cir. 1992), cert. denied, 507 U.S. 984, 123 L. Ed. 2d 147, 113 S. Ct. 1579 (1993). BMS disputes that proposition, arguing that submission of the protocol was voluntary because FDA regulations did not require a post-marketing study. Information is submitted involuntarily, however, if it is supplied pursuant to statute, regulation or some less formal mandate. <u>National Parks</u>, 498 F.2d at 770. In this case,</u>

submission of the protocol was necessary in order to obtain FDA approval, see <a href="McDonnell Douglas Corp. v. National Aeronautics & Space Admin., 895 F. Supp. 316 (D.D.C. 1995),">McDonnell Douglas Corp. v. National Aeronautics & Space Admin., 895 F. Supp. 316 (D.D.C. 1995), and was therefore required.</a>

----- End Footnotes--------

### [\*\*4]

FDA's regulations implementing FOIA provide that "no data or information contained in [a new drug application] is available for public disclosure before the agency sends an approval letter" to the sponsor. 21 C.F.R. § 314.430(d). Once an approval letter has been sent, certain data and information are immediately available for disclosure "unless the applicant shows that exceptional circumstances exist." 21 C.F.R. § 314.430(e). Study protocols are expressly covered by the regulations and are immediately disclosable unless they fall "within the exemption established for trade secrets and confidential commercial information." 21 C.F.R. § 314.430(e)(3).

## [\*415] 1. Impairment

\*\*In order to support a decision to withhold disclosure under the-"impairment" prong of the National Parks test, an agency must demonstrate that disclosure of the withheld information will result in a diminution of the "reliability" or "quality" of necessary future information. Critical Mass, 975 F.2d at 878. FDA argues that data submitted to the agency as part of its drug approval process "would not be submitted as freely" if the protocol is disclosed. (Hooton Decl. P 12). That argument is unsupported, [\*\*5] even by an assertion of agency experience on the point. FDA's conclusory assertion of impairment does not sustain its burden of justifying nondisclosure.

#### 2. Competitive Harm

to avoid disclosure must show (i) actual competition and (ii) likelihood of substantial competitive injury. National Parks, 498 F.2d at 770. No showing of competitive harm can be made if the information at issue is publicly available through other sources. CNA Fin. Corp. v. Donovan, 265 U.S. App. D.C. 248, 830 F.2d 1132, 1154 (D.C. Cir. 1987), cert. denied, 485 U.S. 977 (1988). An additional factor that may be considered is whether there is a strong public interest in release of the information. See Teich v. FDA, 751 F. Supp. 243, 253 (D.D.C. 1990)(benefit of releasing information about safety test results for a medical product "far outstrips the negligible competitive harm that defendants allege"); AT&T Info. Systems, Inc. v. GSA, 627 F. Supp. 1396, 1403 (D.D.C. 1986).

There are currently twenty manufacturers of oral diabetes therapies. Metformin is the leading branded therapy, holding 20% of the [\*\*6] market share. (Rader Decl. P 3). Parke-Davis has recently obtained approval to market Troglitazone, a drug for non-insulin dependent diabetes mellitus, which will compete with BMS's Metformin. (Rader Decl. P 7). The existence of actual competition is well established and, in any case, undisputed.

The likelihood of "substantial competitive injury," however, cannot be measured, or even plainly identified, on this record. The BMS argument that disclosure of the protocol will allow competitors to raise "alarmist" safety concerns is too broad and too speculative to be credited. If critics of Metformin wanted to raise alarms, they could do so using information that is already publicly available. n2 The BMS assertions that disclosure of the protocol

could lead to patient drop-out, bias in the results, and delays in the study's completions are
likewise generalized and unsubstantiated, especially in the absence of any detailed
presentation of which information in the protocol, if any, could threaten the success of the
study.

n2 It is questionable whether the competitive injury associated with "alarmism" qualifies under Exemption 4 in any event. Competitive harm refers to "harm flowing from the affirmative use of proprietary information by competitors," <u>CNA Financial Corp., 830 F.2d at 1154</u>, and not to adverse public reaction. Id. (no competitive harm in disclosure of affirmative action data, despite showing of customer and employee disgruntlement).

_	_		_	_	_	 _	 _	_		Fnd	Footnotes-	_	_	_	_	_	 _	_	_	 _	_	_	<b>F</b> *	*	7	1
-	_	-	_	-	_	 _	 _	_	_	LIIU	LOOKHOLES-												•		4	

BMS comes closer to stating a claim of competitive harm with its argument that disclosure of the protocol would provide "insight" into Metformin's pre-approval test results and BMS's future marketing strategies. Data resulting from pre-approval testing have been discussed by the FDA at open advisory committee meetings, however. BMS has not identified the data, if any, that are not already in the public domain. As to future marketing, the BMS theory that disclosure will let competitors know what will be in Metformin's package insert and the content of BMS' future physician education programs is simply unpersuasive. This record does not reveal how disclosure of the protocol, as opposed to the study results, would lead to such results, or explain why such results would be harmful to BMS.

The central argument put forth by BMS is that disclosure of the protocol would permit its competitors to "piggyback" -- to appropriate the study's design for their own uses. To support this argument, BMS has established that Metformin's protocol is the product of extensive research and manpower (Rohlf Decl. P 6), and that it was designed "according to FDA requirements and input to answer . . . [\*416] the very [\*\*8] specific safety questions of interest" (BMS Opp'n at 6). BMS also asserts the "uniqueness" of its protocol -- that it is designed to generate data about lesser-studied side-effects and involves a large patient base. But BMS does not answer the question posed by plaintiff's affidavits: What advantage would a competitor gain from the protocol for a study that is uniquely tailored to the characteristics of Metformin?

The record as it stands does not present a clear picture as to the competitive injury, if any, that would result from releasing the protocol. In the accompanying order, defendants are directed to submit a copy of the protocol for in camera review. To assist the in camera review, BMS may file, ex parte and under seal, a memorandum identifying precisely the portions of the protocol that contain confidential commercial information which is not already public. Further briefing may be requested following the court's receipt and review of those materials.

JAMES ROBERTSON

United States District Judge

Dated: 2/24/97

## ORDER

Upon consideration of the parties' cross-motions for summary judgment, the opposition thereto, and the entire record, for reasons [\*\*9] stated in the accompanying memorandum, it is this 24th day of February, 1997,

**ORDERED** that FDA submit a copy of the protocol in question for in camera review by March 6, 1997. And it is

**FURTHER ORDERED** that BMS may file an additional memorandum, ex parte and under seal, as described in the accompanying memorandum.

JAMES ROBERTSON

United States District Judge